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09/284,147	03/17/99	LANQUETIN M	GEI-067

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EXAMINER	
QAZI,S	
ART UNIT	**PAPER NUMBER**
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Please find below and/or attached an Office communication concerning this application or pr ceeding.

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 14

Application Number: 09/284,147
Filing Date: April 7, 1999
Appellant(s): Lanquetin et al.

Date mailed 6/11/01

Charles A. Muserlian
Laboratoire Theramex
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed .

(1) Real Party in Interest

A statement identifying the real party Laboratoire Theramex in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

New claim 34 is added after final.

Claims 22-34 are pending.

Claims 22-34 are rejected.

No claim is allowed.

(4) Status of Amendments After Final

The amendment after final rejection filed on 5/8/00 has been entered. New claim 34 falls under the same scope therefore is rejected on the same basis.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is not correct because the issue is that the references of record teaches the instant invention.

Prior art teaches combination of estradiol/progesterone combination is taught for the same use as is instantly claimed. (see claim 1, US '867) such as estradiol and nomegesterol acetate as estrogen alone and then followed by an estrogen progesterone combination and then placebo over the duration of a month.

Note, that 21-25 days are taught by the reference because reference teaches duration of a month.

The treatment by the same combination for extended days would have been obvious to one who is familiar with the art. Note, that the total days of treatment by the prior art is 24

days, 14 consecutive using combination and 10 using estradiol alone.

(7) Grouping of Claims

The rejection of claims 22-34 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof. See 37 CFR 1.192(c)(7).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

The following is a listing of the prior art of record relied upon in the rejection of claims under appeal.

5,891,867	Lanquetin et al.	April 6 1999

Fraser et al. (Medline, AN 89,261,206, abstract of Maturitas, (1989, March), 11(1), 21-34).

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

1. Claims 22-34 are rejected under 35 U.S.C. 103(a) as obvious over Lanquetin et al. (US Patent 5,891,867). Lanquetin teaches a method of treating estrogen deficiencies which embraces applicant's claimed invention.

Lanquetin et al. teaches the method of treating estrogen deficiencies in menopausal women by the oral administration of an estrogen alone followed by the combination of estrogen progestogen combination and then a placebo. See the entire document especially lines 20-62, col. 1, lines 16-67, col. 2, cols 3 and 4, lines 10-64, col. 5. These combination are useful for correction of estrogen deficiencies during natural or artificial menopause.

The instant claims differ from the reference in having different generic scope.

The amended claims now are drawn to the methods of treating hypoestrogenism in women and avoiding the appearance of withdrawal bleeding in post-menopausal comprising orally administering from 21- 25 days simultaneously, an estrogenic compound and a progestogenic compound consisting of nomegesterol

acetate. The 17β-estradiol units for 10 days (D1 to day D10 days).

See US 867, lines 28-59, col. 2, where the delay in the occurrence of bleeding after the treatment was stopped. The 17β-estradiol units for 10 days (D1 to day D10 days). The units of combination of 17β-estradiol and nomegesterol acetate for fourteen consecutive days (day D11 to day D25). The placebo units for six days (day D25 to day D30). See lines 25-62, col. 1). The amount of the active principle ranging from 1-3 mg of β estradiol, combination of estradiol and nomegestrol acetate ranging from 1-3 mg and 1.5 to 6 mg.

The treatment by the same combination for extended days would have been obvious to one who is familiar with the art. Note, that the total days of treatment by the prior art is 24 days, 14 consecutive using combination and 10 using estradiol alone.

Lanquitin et al. teaches that the units of combination of 17β-estradiol and nomegesterol acetate for fourteen consecutive days (day D11 to day D25). The placebo units for six days (day D25 to day D30). See lines 25-62, col. 1). The amount of the

active principle ranging from 1-3 mg of β estradiol, combination of estradiol and nomegestrol acetate ranging from 1-3 mg and 1.5 to 6 mg. The delay in the occurrence of bleeding after the treatment was stopped. See lines 28-59, col. 2.

Claim 1 of the reference is not limited to any number of days for the treatment and therefore, instant invention is considered obvious and may be possible double patenting over the reference.

One having ordinary skill in the art would have been motivated to prepare additional beneficial composition and method for the treatment of estrogenic deficiencies during menopause. the combination with a estrogen and a compound with progestational activity because prior art teaches that estradiol in combination with a progestative compound for the treatment of estrogenic deficiencies. The treatment by the same combination for extended days would have been obvious to one who is familiar with the art. Note, that the total days of treatment by the prior art is 24 days, 14 consecutive using combination and 10 using estradiol alone.

There has been ample motivation provided by the prior art to prepare such combination when searching for the compositions of the similar activity.

Claim 26 is drawn to estradiol valerate are known esters and property associated with the estradiol would be expected to estradiol unless any unexpected results are seen.

Claims 27, 30, 32 and 33 are drawn to the doses of the estrogen compound. The determination to employ the optimum ranges of the estrogen compound would have been within the skills of the one familiar with the art.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

2. Claims 22-34 are rejected under 35 U.S.C. 103(a) as obvious over Fraser et al. (Medline, AN 89261206, abstract of Maturitas, (1989 Mar) 11(1), 21-34). Fraser et al. teaches estradiol in combination with a progestative compound for the treatment of estrogenic deficiencies which embraces applicant's claimed invention.

Fraser teaches the effects of the addition of nomegestrol acetate to post menopausal teach addition of progestogen to the oestrogen in order to prevent endometrial abnormalities. See the abstracts.

The instant claims differ from the reference in having different generic scope. The amended claims of instant invention are the selection of the prior art by claiming the simultaneous administration of estrogenic and progestative compounds for estrogenic deficiencies. The amended claims now are drawn to the methods of treating hypoestrogenism in women and avoiding the appearance of withdrawal bleeding in post-menopausal comprising orally administering from 21- 25 days simultaneously, an estrogenic compound and a progestogenic compound consisting of nomegesterol acetate.

One having ordinary skill in the art would have been motivated to prepare additional beneficial composition and method for the treatment of estrogenic deficiencies,

estradiol/progesterone for the treatment of post menopause estrogen deficiencies by using the combination with a estrogen and a compound with progestational activity because prior art teaches that estradiol in combination with a progestative compound for the treatment of estrogenic deficiencies.

There has been ample motivation provided by the prior art to prepare such combination when searching for the compositions of the similar activity.

Claim 26 is drawn to estradiol valerate are known esters and property associated with the estradiol would be expected to estradiol unless any unexpected results are seen.

Claims 27, 30, 32 and 33 are drawn to the doses of the estrogen compound.

The determination to employ the optimum ranges of the estrogen compound would have been within the skills of the one familiar with the art.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill might reasonably infer from the teachings. *In re opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA 1976). A reference is not limited to working examples. *In re Fracalossi* 215 USPQ 569 (CCPA 1982).

Accordingly, the burden of proof is upon applicants to show that instantly claimed subject matter is different and unobvious over those taught by prior art. See *In re Brown*, 173 USPQ 685, 688; *In re Best*, 195 USPQ 430 and *In re Marosi*, 218 USPQ 289, 293.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

(11) Response to Argument

1. The basis of the arguments is that amended claims are allowable and prior art does not teach the treatment for 21-25 days per month as instantly claimed. Examiner respectfully disagree and the instant invention is considered as obvious over the prior art.

The amended claims now are drawn to the methods of treating hypoestrogenism in women and avoiding the appearance of withdrawal bleeding in post-menopausal comprising orally administering from 21- 25 days simultaneously, an estrogenic compound and a progestogenic compound consisting of nomegesterol acetate.

Note, that claim 1 has no time limit and would be a possible double patenting over US 5,891,867.

2. Examiner respectfully disagree with the arguments because the prior art teaches the instant invention. See Fraser references, lines 15 and 16 of abstract, where all patients experienced a regular, progestogen-induced withdrawal bleed each month. Nomegestrol acetate as a potent progestogen are taught.

3. See US '587, lines 28-59, col. 2, where the delay in the occurrence of bleeding after the treatment was stopped. The 17β-estradiol units for 10 days (D1 to day D10 days).

The units of combination of 17b-estradiol and nomegesterol acetate for fourteen consecutive days (day D11 to day D25). The placebo units for six days (day D25 to day D30). See lines 25-62, col. 1).

The amount of the active principle ranging from 1-3 mg of b estradiol, combination of estradiol and nomegestrol acetate ranging from 1-3 mg and 1.5 to 6 mg.

4. Examiner respectfully disagree because the estradiol/progesterone combination is taught by the prior art for the same use as is instantly claimed. The treatment by the same combination for extended days would have been obvious to one who is familiar with the art. Note, that the total days of treatment by the prior art is 24 days, 14 consecutive using combination and 10 using estradiol alone.

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It would have been obvious to one who is familiar with the art to extend the dosage to further avoid the appearance of bleeding in post-menopausal woman.

For the above cited reasons, it is believed that the rejection should be sustained.

Respectfully submitted

5/4/2001

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PRIMARY EXAMINER
Art Unit 1616

SUPERVISORY PATENT EXAMINER
CONFEREE

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